CONRAD LAW & POLICY COUNSEL

1615 L STREET, N.W., SUITE 650 WASHINGTON, DC 20036-5606 202-822-1970 202-822-1971 (FAX) JAMIE@CONRADCOUNSEL.COM WWW.CONRADCOUNSEL.COM

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Angela Nugent, Ph.D.
Designated Federal Officer, EPA Science Advisory Board
Special Assistant to the Director, EPA SAB Staff Office
U.S. Environmental Protection Agency (1400R)
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Public Involvement in EPA Advisory Activities Supported by the SAB Staff Office

Dear Ms. Nugent:

I am writing in response to the request for comments contained in the SAB's May 11, 2011 Federal Register notice (76 Fed. Reg. 27315). I appreciate your email of May 31, in which you indicated that you would like comments to be submitted by June 30. I trust you will still consider these.

I. Background & Qualifications

I am filing these comments on my own behalf, as someone who has worked for a more than a quarter century on issues involving EPA's use of science. I spent 14 years at the American Chemistry Council, where these issues were always in play, and for almost four years have represented a number of clients on the same types of matters. I've published several articles on agency use of science, and I am the creator and managing editor of the Environmental Science Deskbook. I specialize in administrative law, the field of law applicable to the topic of the SAB's notice, and am currently the Vice-Chair of the American Bar Association's Section of Administrative Law & Regulatory Practice. Of particular relevance, in 2008 I participated in an OMB Watch-sponsored committee studying public participation in agency activities.

¹ http://west.thomson.com/environmental-science-deskbook-law-series/5051/16624886/productdetail.

² These comments are my own and do not necessarily reflect the views of the ABA or the Section.

³ http://www.hks.harvard.edu/hepg/Papers/transparencyReport.pdf.

II. Executive Summary

These comments make specific recommendations regarding two of the specific topics identified in the Staff Office's notice. They are limited to the SAB, as that is the entity supported by the Staff Office with which I have the most experience.

Public Involvement in Nomination of Experts for Committees and Panels. The Staff Office generally interprets applicable laws, rules and policies appropriately as they apply to the SAB, although it is too conservative as it interprets the concept of lack of impartiality. The Office should forthrightly recognize that all experts have biases and that the solution is not to disqualify them but to balance them with experts having countervailing biases.

Public Involvement in Meetings and Report Development. The SAB's current approach to public involvement could be summarized as "All Talk, No Interaction." SAB should revamp its public involvement processes to promote more engagement among panelists, Agency staff and external stakeholders, using as its model the kinds of symposia and forums that academics and scientific societies use to ventilate and deliberate on issues – not legalistic frameworks. In particular:

The Charge. The Staff Office could promote the independence of the SAB and increase the quality and acceptance of its work by accepting the charge submitted by EPA as a draft, inviting public comment on it, and negotiating the terms of the charge with the relevant EPA office.

Information-Gathering Sessions. The Staff Office should follow the example of the National Academies and have each SAB panel conduct, at the outset of its work, a public, face-to-face meeting dedicated to gathering information and views regarding the state of the science relevant to the charge. This is the most important recommendation contained in this letter.

Subsequent meetings. These should also be made more interactive, to promote substantive dialogue among panel members and interested experts.

More effective use of written comments. The Staff Office should make the document under review available to the public at the same time that it is being made available to reviewers, give the public adequate time to review it and to formulate comments, and provide those comments to panelists in time for them to read them before their meeting.

III. Public Involvement in Nomination of Experts for Committees and Panels.

As the SAB Staff Office is aware, the process of choosing individuals to serve on the SAB is governed by the Federal Advisory Committee Act (FACA), Federal ethics laws and rules (particularly the rules of the Office of Government Ethics), and the OMB *Peer Review Bulletin*. The Staff Office generally interprets these authorities appropriately as they apply to the SAB, although it is too conservative as it interprets the concept of lack of impartiality.

A. In General

The Staff Office appropriately treats members of the SAB as "Special Government Employees," thus subjecting them to the Federal ethics laws and rules. The Staff Office has wisely not adopted the view of some agencies (e.g., DOI, DOE and USDA) that experts serving on advisory bodies are "representatives" of interests and thus exempt from ethics requirements.⁴ The Staff Office correctly interprets FACA's "fairly balanced" requirement to refer to the range of respectable scientific and technical perspectives on an issue and not to political perspectives.⁵

B. Over-Conservatism Regarding Appearance of Lack of Impartiality

I am concerned, however, that the Staff Office has been overly conservative in its interpretation of the OGE rules regarding the appearance of lack of impartiality.⁶ In a meeting on June 22 sponsored by the Small Business Administration's Office of Advocacy, former SAB Deputy Director Tony Maciorowski stated that the Staff Office had not issued a waiver of this requirement in the past ten years, at least. In effect, any public statement by a person that tends to indicate a view on a relevant issue, or any potentially biasing employment, has resulted in such persons being rendered ineligible for service on a panel. I would recommend that the Staff Office review the

Science Advisory Board 10 (Sept. 2002), available at

⁴ GAO, the Administrative Conference of the United States and public interest groups have all opposed this practice. *See* Government Accountability Office, GAO-04-328, *Federal Advisory Committees – Additional Guidance Could Help Agencies Better Ensure Independence and Balance* 13 (April 2004); ACUS Recommendation 89-3, *Conflict-of-Interest Requirements for Federal Advisory Committees*, 54 Fed. Reg. 28969 (July 10, 1989); Center for Progressive Reform, *Saving Science from Politics: Nine Essential Reforms of the Legal System* 25 (2008). ⁵ SAB, *Overview of the Panel Formation Process at the Environmental Protection Agency*

http://yosemite.epa.gov/sab/sabproduct.nsf/WebFiles/OverviewPanelForm/\$File/ec0201 0.pdf; *accord* OMB, *Final Information Quality Bulletin for Peer Review*, 70 Fed. Reg. 2664, 2669 (Jan. 14, 2005).

⁶ 5 C.F.R. § 2635.502.

statements of the National Academies, and even EPA's own *Peer Review Handbook*, on this topic. For example, the National Academies Policy states that:

Questions of lack of objectivity and bias ordinarily relate to views or positions taken that are largely intellectually motivated or that arise from the close identification or association of an individual with a particular point of view or the positions of a particular group.⁷

It adds that such biases should not be disqualifying – even where a person works for a company with "a general business interest in" the subject of the panel -- unless the person "is totally committed to a particular point of view and unwilling, or reasonably perceived to be unwilling, to consider other perspectives or relevant evidence to the contrary." The National Academies Policy is widely supported, from industry groups to NGOs. ⁸

The Peer Review Handbook similarly recognizes that "experts with a stake in the outcome – and therefore a conflict or appearance issue – may be some of the most knowledgeable and up-to-date experts because they have concrete reasons to maintain their expertise." Consistently with the National Academies Policy, it states that, "[a]s a general rule, experts . . . who have clearly 'taken sides,' may have an appearance of a lack of partiality . . . and should be avoided." ¹⁰

These statements regarding the correlation of "interest" issues and expertise have been empirically confirmed by the FDA. An FDA contractor studied the issue and found that advisory committee members who were given conflict of interest waivers had greater levels of expertise than those that were not.¹¹ Presumably a similar correlation would hold between appearances of lack of impartiality and expertise.

Outside of cases of conflict or extreme bias, the National Academies' solution is not to disqualify people with biases, but to appoint other people with offsetting biases:

⁷ National Academies, *Policy on Committee Composition & Balance and Conflicts of Interest for Committees Used in the Development of Reports* 3 (May 12, 2003), available at http://www.nationalacademies.org/coi/bi-coi_form-0.pdf.

⁸ For example, the Center for Progressive Reform states: "As the [National Academies'] guidelines recognize, some degree of bias is unavoidable.... On the other hand, when biases become so strong that they impinge on an individual's ability to objectively answer new questions, that person should not be given the institutional power of an advisory committee member." *Saving Science from Politics, supra* note 4.

⁹ EPA Science Policy Council, PEER REVIEW HANDBOOK 70 (3d ed. May 2006), *available at* http://www.epa.gov/peerreview/pdfs/Peer%20Review%20HandbookMay06.pdf.

¹⁰ *Id.* at 63 (emphasis added).

¹¹ ERG, Measuring Conflict of Interest and Expertise on FDA Advisory Committees (2007), available at http://www.fda.gov/oc/advisory/ergcoireport.pdf

"Indeed, it is often necessary, in order to ensure that a committee is fully competent, to appoint members in such a way as to represent a balance of potentially biasing backgrounds or professional or organizational perspectives." This solution is also advocated by the seminal report of the Bipartisan Policy Center (BPC)'s Science for Policy Project: "[T]he goal should be to ensure that the overall committee is balanced." 13

I submit that the Staff Office would benefit by applying the standards of the National Academies, the BPC and the *Peer Review Handbook*, looking for the individuals with the greatest expertise on the relevant topics, accepting public statements or employment in connection with the issue unless they indicate an unwillingness to consider issues fairly,¹⁴ and issuing waivers of the requirement for lack of impartiality in appropriate circumstances.¹⁵

C. SAB's Public Involvement Process

The SAB's process of involving the public in its choice of experts may well be a best practice across the Federal government. The wide cast/narrow cast process appropriately:

- Solicits nominations of potential panelists from the public (even the National Research Council does not do this); and
- Solicits public comments on the draft slate of panelists.

The SAB should continue this process. I would make one recommendation here, designed to help establish a panel's independence from EPA: the Staff Office should require EPA to nominate any potential reviewers that it would like to suggest, and it should note the identity of the nominating person or entity when it posts the lists of proposed and final panelists.

¹³ BPC, IMPROVING THE USE OF SCIENCE IN REGULATORY POLICY 24 (August 2009), available at http://www.bipartisanpolicy.org/sites/default/files/BPC%20Science%20Report%20fnl.pd f.

¹² National Academies Policy, *supra* note 7, at 3.

¹⁴ For example, a statement that no further research on a topic would be warranted, or service as an expert witness in litigation, might indicate that a person is "totally committed to a particular point of view and unwilling, or reasonably perceived to be unwilling, to consider other perspectives or relevant evidence to the contrary."

¹⁵ I would also urge the Staff Office to apply the standards of the *Peer Review Bulletin* in assessing the potential for Agency funding to render a prospective panelist not independent. *See* 70 Fed. Reg. 2669.

IV. Public Involvement in Meetings and Report Development.

A. My Organizing Principle: Look More to Science than Law

I commend the Staff Office for convening the June 1 meeting and inviting input on the topic of involving the public in meetings of the SAB and otherwise in their development of reports. I have a series of recommendations, explained below. Part of the motivation for these recommendations is the due process intuition that, in a free and democratic nation, persons who are affected by the work of a government agency (including its advisory bodies) are entitled to have an appropriate amount of input into those decisions.

But the Staff Office should not regard this issue solely as one of satisfying legalities. Of at least equal importance is the likelihood that external parties have greater scientific and technical expertise than Agency staff and potentially even members of SAB panels. The Staff Office's procedures should be designed to take maximum advantage of that expertise.

Indeed, my recommendations are that those procedures should be *less* legalistic than they are now, and should more closely resemble the norms of scientific discourse in which panel members accustomed to engaging in their normal professional lives, outside of their service on SAB. "Opportunities for comment" and "responses to comments" are really creatures of administrative law, designed to reassure judges. I challenge the Staff Office to develop public involvement processes that are modeled on the dialogic processes used by scientific bodies and societies to try and assess the weight of the relevant evidence and the merits of competing explanatory hypotheses. SAB should not become "science courts," but they could do a better job of serving as scientific bodies.

B. The Charge

Logically and temporally, the first step in improving public involvement in the work of the SAB is to improve the way the charge for these bodies is developed. The Staff Office has heard repeated complaints from panel members, as well as the public, about charges that seem to be drafted intentionally to divert panels' attention from issues that EPA would prefer to avoid. A prominent recent example is the SAB's work on the IRIS assessment for inorganic arsenic, in which SAB members complained about "the elephant in the room here" – the narrowness of the charge questions:¹⁶

¹⁶ SAB, Quality Review Teleconference (Nov. 22, 2010), transcript at 155.

[G]iven that there is a fair amount of discomfort both from the public comments and from several members of the SAB around that ... narrow focus[, the SAB should offer to] do an integrated review . . ., in fact, do what I think everyone really had hoped we would do from the get-go.¹⁷

At present, EPA largely presents the charge to the Staff Office as a fait accompli. I recommend that the Staff Office essentially follow the model of the NRC:

- Accept the charge submitted by EPA as a draft.
- Publish a notice of the draft charge, inviting public comment on it. This will enable the staff office to gain the benefit of others' views on relevant issues and how the charge might ideally be phrased.
- Negotiate the terms of the charge with the relevant EPA office, both before and after those comments are received. 18
- Permit the panel to seek to renegotiate the charge with EPA (through the Staff Office) where panel members feel that is truly warranted.

The foregoing steps should maximize the likelihood that the charge:

- Addresses the full range of relevant issues;
- Does not presuppose any conclusions; and
- Avoids tasking SAB with answering policy questions.

They will also help ensure that the SAB is truly independent of EPA, as it prides itself in being.19

Based on this charge, the Staff Office can then choose a panel that contains the range of expert perspectives that the charge question(s) require. (This process is discussed in Part III above.)

C. The Information Gathering Session

Of all the recommendations in this submission, the one requiring the most dramatic departure from current Staff Office practice is this one: that all SAB panels should conduct, at the outset of their work on any particular charge, a public, face-to-face meeting dedicated to gathering information and views regarding the state of the science relevant to the charge. This is not a novel concept for advisory bodies - NRC panels typically conduct an information-gathering session as part of their first meeting. And EPA begins the process of each five-year NAAQS revision by holding a

¹⁷ *Id*. at 117.

¹⁸ Among other things, the SAB might choose to avoid answering essentially editorial charge questions about how well a document is drafted, etc.

¹⁹ See Overview of the Panel Formation Process, supra note 5, at 2.

public workshop to determine the state of the policy-relevant science as of that point. But SAB panels have not customarily begun their deliberations with this sort of forum, and I submit this omission has rendered some panels' work unnecessarily complicated and has lessened the quality of their final reports from what it could have been.

In essence, the purpose of an information gathering session is "crowd-sourcing"; to ensure that the panel is aware of the full range of relevant information, as identified by interested stakeholders, and the perspectives of those stakeholders as to:

- which studies are most significant and why;
- which studies may be confounded or have other shortcomings;
- which modes of action are most plausible; and
- the major sources of uncertainty.

In order for these sessions to be most productive, they should begin with a presentation by EPA staff regarding the work (or question) to be reviewed and the reasons motivating the charge question. Panel members would be encouraged to question staff.

Following the EPA presentation, but while Agency staff remained, interested stakeholders would be given time to make presentations regarding the relevant science. Again, panel members would be encouraged to question the presenters. A facilitator (which could be the panel chair, the DFO for the panel, or a contractor), would administer this portion of the process. These presentations could be timelimited, but those limits should be scaled to the importance of the issue and the amount of information that each presenter seeks to convey. They could well vary depending on the presenter. They should not be arbitrarily limited to three or five minutes, however.

Ideally, the panel would allow the various presenters, EPA and stakeholder representatives, to ask each other questions and engage in debate. For example, presenters might be seated at tables where they could remain and engage in discussion after they had concluded their individual presentations. Certainly the Staff Office should experiment with this approach. If it determined that the process was too difficult to manage effectively, the process could be conducted like Congressional hearings; i.e., stakeholders and Agency staff would not permitted to question each other, but panel members could ask each questions raised by the other.

In appropriate cases, it might be worthwhile for the facilitator to present a relevant analytical framework (e.g., the IPCS Framework for Analyzing the Relevance of a Cancer Mode of Action for Humans) and invite presenters to explain how they

would apply it to the existing body of science. Presenters might also be invited to prepare standardized evidence tables illustrating their analysis of the literature. Such a focused set of presentations and discussions could be particularly useful when the SAB is being asked to review an IRIS assessment.

In designing and piloting this process, the Staff Office should be motivated principally by the desire to facilitate and maximize authentic engagement among professionals – as opposed to the current "all talk, no interaction" approach. The Staff Office should use as its model the kinds of symposia and forums that academics and scientific societies use to ventilate and deliberate on issues.

Inherent in this proposal is that presenters would have scientific or technical expertise, as indicated by job title, academic credentials, authorship of papers or articles, etc. On topics of great public controversy, it might be necessary to have a separate public comment period for individuals not claiming (or credibly able to substantiate) such expert status. Implementing this distinction will require some degree of judgment, but it should not be a sufficient reason not to pursue the idea.

It is often difficult for the regulated community to ascertain the basis for the Agency's selection of studies, or choice of methodology for assessing risk, and as a result some conclude that EPA is attempting to covertly bias the reports that it issues. Greater participation by Agency scientists in forums of this sort would demonstrate a willingness to delineate the bases for those choices and engage in discussion on their merits, and could go a long way toward dispelling such perceptions of bias.

D. Subsequent Sessions

The SAB currently receives public comments at designated periods during its face-to-face meetings. It should continue to involve the public at public meetings after the proposed information gathering/state of the science session. While these public input opportunities need not be structured like that event, the Staff Office should undertake to make all of them more interactive, to promote substantive dialogue among panel members and interested experts.

E. Written Comments

For "highly influential scientific assessments," OMB's *Peer Review Bulletin* requires that,

[w]henever feasible and appropriate, the agency shall make the draft scientific assessment available to the public for comment at the same time it is submitted for peer review (or during the peer review process) and

sponsor a public meeting where oral presentations on scientific issues can be made to the peer reviewers by interested members of the public. When employing a public comment process as part of the peer review, the agency shall, whenever practical, provide peer reviewers with access to public comments that address significant scientific or technical issues. To ensure that public participation does not unduly delay agency activities, the agency shall clearly specify time limits for public participation throughout the peer review process.²⁰

Following this direction, and as a best practice in cases that might not meet the definition of "highly influential scientific assessments," the SAB should:

- Notify the public of the availability of the report (or other materials) being supplied to the panel, at the same time that it is being made available to reviewers;
- Give the public adequate time to review the report and to formulate comments (generally 30 days, and potentially longer for major documents; and
- Provide the public comments to the reviewers in time for them to be able to read them before the panel's meeting (at least a week). The Staff Office should design its website such that comments filed electronically would be automatically posted on the site and an email notice sent to panel members notifying them that comments had been posted and of the identity of the commenter. The Staff Office should not collect comments and then submit them to reviewers in batches.

Notably, I am not recommending that SAB prepare "response to comments" documents addressing the comments submitted by the public. Such exercises are an example of the legalistic model that I am urging the Staff Office to avoid emulating. If the panels' reports are thorough and the comments are raise important issues, the report will by necessity end up addressing those topics. If it does not, that omission will be obvious and will not reflect well on the report or the panel members.

F. Feasibility

In making the foregoing proposals, I am sensitive to concerns that they will require additional meeting time and staff effort, and would be risky (as all innovations are). However, I also note Mr. Maciorowski's statement at the June 22 SBA session that 70% of SAB meetings have no public comments. I should think it would be a rare

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²⁰ 70 Fed. Reg. 2676.

review where the initial information gathering session could not be conducted in a single day or less.

While these recommendations might encourage a greater degree of participation, it seems likely that, in most cases, no one will sign up for the public involvement aspect of meetings, and things will proceed as they do now. And to the extent that these proposals to engender greater public participation, I posit that this will be a good thing from the perspective of improving the overall quality of the SAB' work.

* * *

Once again, I commend the Staff Office for seeking the public's views on how to increase public involvement in the SAB' formation and report development. As can be seen, I think doing so will only increase the quality of those reports, as well as the credibility of the SAB. I encourage the Staff Office to be bold in its innovations, and thank you for the opportunity to provide you with these recommendations.

Sincerely,

James W. Conrad, Jr.

Thomason